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MILLEN, WHITE, ZELANO & BRANIGAN, PC
2200 CLARENDON BLVD
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,697	COUCH ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-28 is/are rejected.

7)☒ Claim(s) 2-11,20 and 28 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/13/04 and 4/1/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-28 are presented for examination.

Applicant's claim for priority under 35 U.S.C. 119(e) to United States Provisional Patent Application Nos. 60/445,793, filed February 10, 2003, and 60/473,925, filed May 29, 2003, is acknowledged. Applicant's Information Disclosure Statements (IDS) filed September 13, 2004 and April 1, 2005 have been received and entered into the application. As reflected by the attached, completed copies of substitute form PTO-1449 (four pages in total), the Examiner has considered the cited references.

Objections to the Claims

Claims 2-11 are objected to under 37 C.F.R. 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claim 1. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. For example, the limitation "...wherein said earlier period is the time before about 1:00 pm of a given day and said later period is the time thereafter" (see lines 1-2 of present claim 2) does not impart any physical or otherwise material property to the composition that is not already present in the composition as recited in claim 1. The same rationale applies to claims 3-11, but for the difference in the recited limitation(s).

Claim 20 is objected to for reciting "A method according to claim 1...". Claim 1 is drawn to a pharmaceutical combination, not a method. Appropriate correction to the claims is required. For the purposes of examination, the claim will be interpreted as being dependent on method claim 16.

Claim 28 is also objected to under 37 C.F.R. 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claim 27. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. The limitation "...wherein inattentiveness later in the day is treated as effectively by said l-isomer as with a corresponding molar amount of d-amphetamine and with a lesser side effect of sleep deterioration and/or decrease in food intake" (see lines 1-3 of present claim 28) does not further limit the method steps recited in the claim from which it depends, but is merely a statement of the efficacy of the pharmaceutical combination.

Appropriate correction to the claims is required.

Objections to the Specification

The Examiner has noted the incorporation by reference of PCT Publication WO 00/23055 at page 1, lines 9-10 of the disclosure. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. See 37 C.F.R. 1.57(f).

The use of the trademarks DEXEDRENE®, DEXTROSTAT®, ADDERALL®, ADDERALL XR®, STRATTERA® has been noted in this application at page 1, lines 11-12 and

15, for example. Each letter of the trademark should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. The citation of the above page in the present specification is not intended to be an exhaustive list of all of the trademarks used in the disclosure or all of the places at which trademarks have been improperly used. Applicant is respectfully requested to capitalize all trademarked names and each should be accompanied by the generic terminology.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 32, lines 16 and 23. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I Claims 1-15 and 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

While Applicant has claimed particular release characteristics of the pharmaceutical combination of claim 1 by the recitation of "...wherein the molar ratio of l-amphetamine to d-amphetamine released therefrom in a time period later in the day is higher than said ratio

released therefrom in a time period earlier in the day" (see claim 1, lines 2-4), it is clear that Applicant has omitted elements of the combination that are essential to such a release profile. Applicant states the following at page 10, lines 11-22 and page 11, lines 31-32:

> "The release profiles of amphetamine can be accomplished routinely with a wide variety of conventional formulations, e.g., with structures such as solids having an essentially homogeneous composition or multiple layers, beads, matrices, materials which provide osmotically driven delivery, compartmental delivery forms (e.g., transdermal patches, osmotic forms, etc.), and various combinations thereof (e.g., layers on beads, different bead compositions and configurations mixed together in a capsule or separately provided, different ratios of isomers in different compartments, e.g., of a patch, device, composition etc., any of which can be formulated for immediate, extended, delayed, etc. release. Formulations for achieving the foregoing dosing regimens are conventional. These can use immediate, controlled, sustained, extended, pulsatile, etc. technologies, alone or in combination to achieve the desired regimens [see page 10, lines 11-22]...Various polymeric materials can be used to achieve the desired type of pattern of release, e.g., immediate, sustained, delayed etc. release [see page 11, lines 31-32]."

Applicant has provided particular examples of pharmaceutical combinations at pages 34-39 of the disclosure describing particular pharmaceutical combinations that are within the scope of Applicant's invention. However, because Applicant has not specifically claimed the vehicle, the components of the vehicle, the formulation or other additives that are relevant to establishing a pharmaceutical combination wherein more d-amphetamine is released immediately and more l-amphetamine is released later, the claims are considered to be incomplete.

Absent such limitations, the recitation of the release profile of the l-isomer and the d-isomer of the combination does not impart any physical or material property to the combination that is not already present. As a result, the claims are not considered to distinguish over a pharmaceutical combination simply comprising amphetamine in base and/or salt form. The release characteristics that Applicant has ascribed to such a composition are considered immaterial to the fact that amphetamine in base and/or salt form is required to be present in such

a pharmaceutical combination. However, if Applicant intends to claim a particular pharmaceutical formulation of d- and l-amphetamine in which the d- and l-isomers are released at different times, then any elements considered essential to such a formulation, particularly the type of delivery system (i.e., immediate release capsule, bead formulation, etc.), the components of such a delivery system (i.e., a particular enteric coating, solvent, carrier, etc.) or a polymer that aids in the immediate release of d-amphetamine and delayed release of l-amphetamine, should be recited in the claims. Applicant is required to particularly point out and claim that which he regards as the invention; in light of the disclosure, it appears that Applicant has omitted physical and/or structural elements that are considered material to the composition in order to obtain the release characteristics as claimed.

For the purposes of examination, the claims will be examined insofar as they read upon the physical or material limitations of the combination (i.e., that amphetamine must be present in an effective amount in base and/or salt form).

II Claims 4, 10, 12, 20 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following at §2173:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expression "about 4/1 to about 2/1" (see claim 4, for example) is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether or not the molar ratio of d- to l-amphetamine is included in or excluded from the present claims and what degree of variability outside the recited ratio is within the scope of the claims. It is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims. Thus, the claims do not meet the tenor and express requirements of 35 U.S.C. §112, second paragraph and are properly rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I Claims 1-11 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Burnside et al. (U.S. Patent No. 6,322,819; 2001).

Burnside et al. teaches a multiple pulsed dose drug delivery system for administering amphetamine salts and mixtures thereof (col.3, lines 16-20), wherein the composition provides immediate release and enteric release (each pulsed type release) of one or more amphetamine

salts and mixtures thereof. Burnside et al. teaches pharmaceutically active amphetamine salts, such as amphetamine base and all chemical and chiral derivatives and salts thereof, and also teaches that all other compounds indicated for the treatment of attention deficit hyperactivity disorder may also be used (col.7, lines 48-55).

While the Examiner has considered the limitations recited in present claims 2-11, 14-15 and 22-26, the recitation of the release profile of the l-isomer and the d-isomer of the combination (nor any further limitations thereof; see present claims 1-11, for example) or the regimen of administration (see present claims 22-26, for example), does not impart any physical or material property to the combination that is not already present. The release characteristics that Applicant has attributed to the combination are considered immaterial to the fact that amphetamine in base and/or salt form is required to be present in the combination. As a result, the claims are not considered to distinguish over a pharmaceutical combination simply comprising amphetamine in base and/or salt form, which is clearly taught in the prior art of Burnside et al.

Furthermore, Burnside et al. teaches that the disclosed drug delivery system can be used in the administration of amphetamine salts (e.g., amphetamine base and all chemical and chiral derivatives and salts thereof) and mixtures thereof (col.7, lines 48-55). Such is considered by the Examiner to meet the limitation of "base and/or salt form", since the reference clearly anticipates the use of base alone, base and salt, or salts alone, and within each any chemical or chiral derivatives of base, salt, or base and salt.

II Claims 1-15 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Patrick et al. ("Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit Hyperactivity Disorder", 1997; p.527-546).

Patrick et al. teaches dextroamphetamine and levoamphetamine mixed salts, marketed and sold under the brand name ADDERALL® in the treatment of attention deficit hyperactivity disorder (ADHD). Patrick et al. discloses that ADDERALL® is a combination product comprising dextroamphetamine saccharate, dextroamphetamine sulfate, racemic amphetamine aspartate and racemic amphetamine sulfate (page 537, col.2, last paragraph). Patrick et al. also teaches that the total free base equivalence in, for example, a 10 mg tablet is 6.3 mg, of which 81% is dextroamphetamine and 19% is levoamphetamine (see also page 537, col.2, last paragraph).

Furthermore, Patrick et al. further teaches that the recommended dosage for the treatment of ADHD is 5 mg once or twice per day (considered by the Examiner to meet the limitation of two separate oral dosage forms; see Table 3 at page 535 which states a table formulation of ADDERALL®) with incremental increases of 5 mg/week until optimal response is established, but generally not to excess 40 mg/day. Although the reference does not specifically teach a range of amphetamine between 1 and 200 mg/day (see present claim 12), Patrick et al. anticipates the range insofar as it reads upon a dose of amphetamine of 5-40 mg/day (see MPEP § 2131.01 regarding rejections under 35 U.S.C. § 102 of ranges).

While the Examiner has considered each of the limitations recited in present claims 1-11, 14-15 and 22-26, the recitation of limitations regarding the release profile or the regimen of administration does not impart any physical or material properties to the combination that is not

already present in the pharmaceutical product taught by the disclosure of Patrick et al. and, thus, do not further limit the combination claims. For these reasons and those of record in the preceding section (see "Claim Rejections-35 U.S.C. 102" under Section Heading I), the claims are not considered to distinguish over a pharmaceutical combination simply comprising amphetamine in base and/or salt form, which is clearly taught by Patrick et al.

In addition, the recitation of the efficacy of the treatment method (see present claim 28) is also not considered to further limit the method steps of the claim from which it depends (see present claim 27). While such a limitation has been considered by the Examiner, it does not impart any additional limiting steps or processes to the method that are not already present in the method of treatment as disclosed by Patrick et al. The reference, therefore, properly anticipates the claim.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patrick et al. as applied to claims 1-15 and 27-28 above, and further in view of Epstein et al. (WO 2002/039998; 23 May 2002), Applicant's acknowledgement at page 10, line 20-page 11, line 4, STN Registry file (Registry No. 156-34-3) and Tulloch et al. ("SLI381 (Adderall XR), a Two-Component, Extended Release Formulation of Mixed Amphetamine Salts: Bioavailability of Three Test Formulations and Comparison of Fasted, Fed and Sprinkled Administration", Pharmacotherapy, 2002;22(11):1405-1415).

The differences between the Patrick et al. reference and the presently claimed subject matter lie in that the reference does not teach:

(i) the dose of the combination from 1-4 mg and 41-200 mg/day;

(ii) the administration of a composition of amphetamine wherein the molar ratio of l-isomer to d-isomer is greater than 1:3;

(iii) the administration of a composition of the l- and d-isomers of amphetamine in a single staged-release, immediate release, pulse release and/or sustained or controlled release dosage forms; and

(iv) the administration of an amphetamine composition in two doses, the first having an l/d isomer ratio of about 1:3 or contains only d-isomer and the second dose having an l/d isomer ratio of greater than about 1:1 or contains l-isomer only.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) The determination of the optimum dosage regimen to treat ADHD with the presently claimed active agent would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan. Applicant's attention is further drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." Although the present set of facts are drawn to mg/day dosages, the motivation as drawn from the MPEP at §2144.05 is nonetheless relevant.

(ii) Although Patrick et al. teaches an amphetamine composition wherein the composition contains more d-isomer than l-isomer, the reference is silent as to the administration of an amphetamine composition wherein the composition contains more l-isomer than d-isomer.

However, one of ordinary skill in the art would have been motivated to modify the composition disclosed by Patrick et al. to administer more l-isomer than d-isomer in light of the disclosure of Epstein et al., who states, "In particular, we describe herein the use of pharmaceutical preparations for increasing long-term potentiation and/or improving long-term memory in animals, such as humans, which include R-(-)-amphetamine or a derivative thereof. R-(-)-amphetamine is at least 4 times more effective as a memory enhancer as compared to the commonly prescribed S-(+) enantiomer of amphetamine. In addition, unlike S-(+)-amphetamine, the R-(-) enantiomer has not been shown to be addictive (page 26, lines 26-32)[1]." Epstein et al. further discloses that the memory impairment may result from attention deficit disorder (see page 16, lines 6-15). It would have been obvious, therefore, to the skilled artisan to modify the composition disclosed by Patrick et al. to include more l-isomer than d-isomer to lessen the addictive side effects of the amphetamine composition and also to improve the efficacy of the composition in treating the symptoms associated with attention deficit disorder.

(iii) Patrick et al. teaches a single dosage formulation containing both d-, l- and racemic amphetamine and amphetamine salts, but is silent as to the preparation of the combination of compounds in an immediate, pulse release and/or sustained or controlled release dosage forms. However, such formulations were well known in the art at the time of the invention (see Applicant's acknowledgement at page 10, line 20-page 11, line 4). It would have been well within the purview of the skilled artisan to employ any one or more of these special release formulations in the preparation of the composition disclosed by Patrick et al. in order to effect the desired release profile of the drug. Such a person would be motivated to do so in order to

[1] Reference "U" is a registry file entry of STN showing that "R-(-)-amphetamine" and "l-amphetamine" are the

alter the release characteristics of the composition to enhance bioavailability and pharmacologic effect.

Furthermore, formulation of composition containing d-, l- and racemic amphetamine as taught by Patrick et al. into a special release preparation (i.e., immediate, pulse, controlled or sustained release) would necessarily contain l-isomer and is, thus, not considered to be a difference between the presently claimed subject matter and the Patrick et al. reference in light of what was known in the art.

(iv) ADDERALL®, the composition taught by Patrick et al., was known in the art to have a dextroamphetamine:levoamphetamine ratio of 3:1 (see Tulloch et al., p.1406, paragraph bridging col.1 and col.2). Patrick et al. further teaches that compositions containing dextroamphetamine only were also known in the art for the treatment of ADHD (see page 536, col.1-2). While Patrick et al. does not disclose a method of treating attention deficit disorder using two doses wherein the second dose has more l-isomer than d-isomer or is all l-isomer, Epstein et al. provides adequate scientific rationale that one skilled in the art would have been motivated to modify the dextroamphetamine/levoamphetamine composition disclosed in Patrick et al. to administer more l-isomer than d-isomer, or even to administer all l-isomer (see page 26, lines 26-32, where Epstein et al. teaches compositions enriched for one enantiomer), due to its enhanced efficacy and reduction in side effects, such as addiction. Furthermore, since each composition was known in the art to be effective for the treatment of attention deficit disorder (see Patrick et al., p.536-538 and Epstein et al., page 16, lines 6-15), it would have been well within the purview of the skilled artisan to employ a two-pronged regimen, wherein two doses of

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same compounds by virtue of their having the same registry number, i.e., "RN".

known amphetamine compositions were administered. Motivation to administer two compositions flows logically from the fact that each was known to be administered for the same therapeutic endpoint. Thus, it would have been *prima facie* obvious to use in combination two or more agents that have previously been used separately for the same purpose.

Rejection of claims 1-28 is deemed proper.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

I Claims 1-15 and 22-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the composition claims of U.S. Patent Nos. 6,605,300 and 6,322,819 and are provisionally rejected over the composition claims of U.S. Patent Application Nos. 11/091,011; 10/758,417; 10/443,151; 11/030,174; 10/673,557; 10/353,073. This rejection is directed solely to the claims of the above-cited patents that define compositions of matter, i.e., the same statutory category of invention.

Due to the number of applicable different patents and patented claims, a detailed analysis of why the presently claimed subject matter would have been an obvious variation over each one of the applicable claims in different patents is not presented, but the rejection set forth below is applicable to all of the above-cited patents but for differences in claim numbering. Claims 1-15 and 22-26 are rejected over claims 1-18 of U.S. Patent No. 6,605,300. For the following reasons, the presently claimed subject matter would have been obvious not only over such claims, but over each of the applicable claims of the remaining U.S. Patents or U.S. Patent Applications cited above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the '300 patent are not considered to be patentably distinct from each other because the patented claims clearly anticipate the present claims. While the claims of the instant application also recite limitations drawn to the release profile of the composition (i.e., more d-amphetamine released earlier in the day than l-amphetamine and more l-amphetamine released later in the day than d-amphetamine), such is not considered to impart any physical or material properties to the composition. In light of such a fact, because the present claims merely require the presence of an effective amount of amphetamine in base and/or salt form, the claims are considered to be anticipated by the '300 patent because the patented claims clearly provide for the active amphetamine component in an effective amount. In addition, the present claims use the word

"comprising", which is considered open transitional claim language and allows for the use of other components with the active agent recited in the present claim (see MPEP §2111.03 [R-2] for a discussion of transitional phrases). Thus, the present claims do not patentably exclude the additional components, such as the enteric coatings or carriers of the patented claims. Furthermore, the Examiner notes that the release characteristics and pharmacokinetic parameters of the composition of the present claims and that of the patent are reasonably expected to be same, absent factual evidence to the contrary. The Examiner is further supported in this position by the MPEP at §2113, which states, "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith."

Accordingly, rejection of claims 1-15 and 22-26 of the present application is deemed proper over each of the above-indicated patents as claiming obvious and unpatentable variants.

II Claims 16-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the method claims of U.S. Patent Application Nos. 11/030,174; 10/673,557; 10/353,073. This rejection is directed solely to the claims of the above-cited patents that define methods of treatment, i.e., the same statutory category of invention.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the copending applications are not considered to be patentably distinct from each other because the present claims clearly anticipate the copending claims. The copending claims require the administration of an amphetamine composition for the treatment of attention deficit hyperactivity disorder, which is clearly anticipated by the present method claims. While the copending claims of U.S. Patent Application No. 11/030,174 and 10/353,073 recite the use of amphetamine compositions with particular mean plasma concentration profiles, such pharmacokinetic properties are considered to be an inherent property of the composition and cannot be separated from the composition itself. Therefore, because the present claims clearly provide for the active amphetamine composition and the therapeutic objective of treating ADHD, the Examiner considers the present method claims to anticipate the method claims of the copending applications listed above.

Accordingly, rejection of claims 16-21 of the present application is deemed proper over each of the above-indicated copending patent applications as claiming obvious and unpatentable variants.

Conclusion

Rejection of claims 1-28 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096.

The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

May 25, 2005

RAYMOND HENLEY III
PRIMARY EXAMINER
AU 1614